MAR 19 2008

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k080166

Submitter's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952) 368-7899
Fax: (952) 368-7610
Contact: Jeffrey L. Koll

Date Prepared: March 11, 2008

Device Names

Proprietary Name: Access® Estradiol Calibrators on the Access® Immunoassay Systems

Common Name: Calibrators

Classification Name: Calibrator, Secondary (862.1150, JIT)

Predicate Device

Access Estradiol Calibrators
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

510(k) Number: k973743, k970126

Device Description

The Access Estradiol Calibrators are liquid calibrators to be used with the Access Estradiol assay to generate the estradiol calibration curve on the Access Immunoassay Systems. The Access Estradiol Calibrator kit contains six vials, one for each calibrator level. The Access Immunoassay Systems utilize a competitive binding immunoenzymatic assay for the quantitative measurement of estradiol.

Intended Use

The Access Estradiol Calibrators are intended to calibrate the Access Estradiol assay for the quantitative determination of estradiol levels in human serum and plasma using the Access Immunoassay Systems.

Summary of Technological Characteristics

Attribute	Access Estradiol Calibrators	Access Estradiol Calibrators (restandardized)
Intended Use	Calibration for quantitative determination of estradiol levels in human serum and plasma	No Change
Calibrators	Estradiol at approximate levels of 100, 500, 1500, 2500, and 3600 pg/mL, liquid	Estradiol at approximate levels of 106, 570, 1800, 3100, and 4800 pg/mL, liquid
Traceability	Traceable to USP reference material	Traceable to ID-GC/MS (isotope dilution-gas chromatography/mass spectrometry) reference method

The device modification consists of restandardizing the Access Estradiol Calibrators traceability from USP reference material to the ID-GC/MS reference method. There is no change to calibrator materials, functionality, or stability.

Conclusion

The restandardization of the Access Estradiol Calibrators does not change the intended use or indications for use, alter the fundamental scientific technology, or affect the safety and efficacy of the device. Performance data generated from validation testing demonstrates that the restandardized Access Estradiol Calibrators on the Access Immunoassay Systems is substantially equivalent to the currently commercialized Access Estradiol Calibrators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Beckman Coulter, Inc.
c/o Mr. Jeffrey L. Koll
Regulatory Specialist
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

MAR 19 2008

Re: k080166
Trade/Device Name: Access® Estradiol Calibrators on the Access® Immunoassay Systems
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrators
Regulatory Class: Class II
Product Code: JIT
Dated: February 19, 2008
Received: February 20, 2008

Dear Mr. Koll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Access® Estradiol Calibrators on the Access® Immunoassay Systems

Indications For Use:

The Access Estradiol Calibrators are intended to calibrate the Access Estradiol assay for the quantitative determination of estradiol levels in human serum and plasma using the Access Immunoassay Systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use

_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

...n Sign-Off

...ffice of In Vitro Diagnostic Device
...luation and Safety

K 080166